

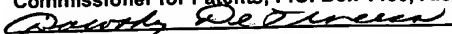
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 06189/HG
INTERNATIONAL APPLICATION NO. PCT/JP2004/016715	INTERNATIONAL FILING DATE 4 NOVEMBER 2004	U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/577,982
TITLE OF INVENTION METHOD OF DETECTING GENETIC POLYMORPHISM		PRIORITY DATE CLAIMED 7 NOVEMBER 2003; 16 APRIL 2004
APPLICANT(S) FOR DO/EO/US Makoto KOIZUMI		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> 1. <input type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The US has been elected (Article 31). 5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). <p>Items 11 to 20 below concern document(s) or information included:</p> <ol style="list-style-type: none"> 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A preliminary amendment. 14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. <input type="checkbox"/> Other items or information: 		

Express Mail Label No. EV 919 330-588-US 339 577 US


DATE OF DEPOSIT: AUGUST 3, 2006

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above with sufficient postage, and is addressed to the Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450



Dorothy DeFrancesco

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/577,982		INTERNATIONAL APPLICATION NO. PCT/JP2004/016715		ATTORNEY'S DOCKET NUMBER 06189/HG	
The following fees have been submitted				CALCULATIONS	PTO USE ONLY
21. <input type="checkbox"/> Basic national fee..... \$300				\$	
22. <input type="checkbox"/> Examination fee If international preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0 All other situations..... \$200				\$	
23. <input type="checkbox"/> Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100 International Search Report prepared and provided to the Office..... \$400 All other situations..... \$500				\$	
TOTAL OF 21, 22 and 23 =				\$	
<input checked="" type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		x \$250	\$	
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	- 20 =		x \$ 50	\$	
Independent claims	- 3 =		x \$200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+ \$360	\$
TOTAL OF ABOVE CALCULATIONS =				\$	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
SUBTOTAL =				\$	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(l)).				+	\$
TOTAL NATIONAL FEE =				\$	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	\$
TOTAL FEES ENCLOSED =				\$	
				Amount to be refunded:	\$.00
				Amount to be charged:	\$.00
<p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>06-1378</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input checked="" type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p>					
<p>NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.</p>					
<p>SEND ALL CORRESPONDENCE TO:</p> <p>CUSTOMER NO. 01933</p> <p>Richard S. Barth Frishauf, Holtz, Goodman & Chick P.C. 220 5TH AVE FL 16 NEW YORK NY 10001-7708</p>					
				<p></p> <p>SIGNATURE</p> <p>Richard Barth</p> <p>NAME</p> <p>28,180</p> <p>REGISTRATION NUMBER</p>	

The PTO did not receive the following listed item(s):

NO credit Card sp

**IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE**

Applicant(s): Makoto KOIZUMI
Serial No. : 10/577,982
Docket No. : 06189/HG
Filed : May 2, 2006
For : METHOD OF DETECTING GENETIC
POLYMORPHISM
Customer No.: 01933

Express Mail Mailing Label
No.: EV 919 339 577 US
Date of Deposit: August 3, 2006
I hereby certify that this paper is
being deposited with the United States
Postal Service "Express Mail Post
Office to Addressee" service under
37 CFR 1.10 with sufficient postage
on the date indicated above and is
addressed to:
MAIL STOP PCT
Commissioner for Patents.
P.O. Box 1450
Alexandria, VA 22313-1450


Dorothy DeFrancesco

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

MAIL STOP PCT

S I R :

In the event that this Paper is late
filed, and the necessary petition
for extension of time is not filed
concurrently herewith, please consider
this as a Petition for the requisite
extension of time, and to the extent
not tendered by Form PTO-2038,
authorization to charge the
extension fee, or any other fee
required in connection with this
Paper to Account No. 06-1378.

This application is a United States national phase
application under 35 USC 371 of International application
PCT/JP2004/016715.

Submitted herewith are the following:

- (1) a copy of the International Search Report for
PCT/JP2004/016715;
- (2) copies of publications cited in the aforesaid
International Search Report;
- (3) copies of publications disclosed on pages 2 to 6 of the
present specification; and
- (4) Forms PTO/SB/08A and PTO/SB/08B.

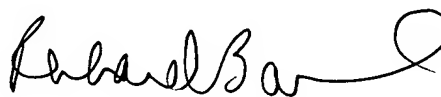
Each of the publications cited in said International Search Report is considered relevant or material to the patentability of the present invention, in view of the citation thereof in said Search Report.

Said International Search Report is in English, thereby satisfying the requirements for a concise explanation of relevance for the publications cited therein.

It is respectfully requested that initialed copies of the enclosed Forms PTO/SB/08A and PTO/SB/08B be returned to the undersigned to indicate that the publications listed therein have been considered and made of record.

Frishauf, Holtz, Goodman
& Chick, P.C.
220 Fifth Avenue, 16th Fl.
New York, NY 10001-7708
Tel. Nos. (212) 319-4900
(212) 319-4551/Ext. 219
Fax No.: (212) 319-5101
E-Mail Address: BARTH@FHGC-LAW.COM
RSB/ddf

Respectfully submitted,



Richard S. Barth
Reg. No. 28,180

- Encs.: (1) Copy of International Search Report
for PCT/JP2004/016715
- (2) Forms PTO/SB/08A and PTO/SB/08B
- (3) Copies of the publications cited on said
forms PTO/SB/08A and PTO/SB/08B

Please type a plus sign (+) inside this box →

+

PTO/SB/08A (08-00)

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/577,982
				Filing Date	May 2, 2006
				First Named Inventor	Makoto KOIZUMI
				Group Art Unit	
				Examiner Name	
Sheet	1	of	3	Attorney Docket Number	06189/HG

U.S. PATENT DOCUMENTS

Exam. Inits ¹	Cite No ¹	Document Number	Kind Code ²	Name of Patentee or Applicant	Publication Date MM-DD-YYYY	Relevant Portion

FOREIGN PATENT DOCUMENTS

Exam. Inits ¹	Cite No ¹	offc ³	Document Number ⁴	Kind Code ⁵	Name of Patentee or Applicant	Publication Date MM-DD-YYYY	Relevant Portion	T ⁶
		JP	3420984	B2	SANKYO CO., LTD.	4-18-2003		*
		JP	2000-297097	A	SANKYO CO., LTD.	10-24-2000		**
		JP	10-304889	A	IMANISHI	11-17-1998		**

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

* EXAMINER: Initial if document considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Place a check here if English translation is attached.

DATE MAILED: August 3, 2006

*PARTIAL ENGLISH-LANGUAGE TRANSLATION ENCLOSED

**ENGLISH-LANGUAGE ABSTRACT ENCLOSED

Please type a plus sign (+) inside this box →

+

PTO/SB/08B (08-00)

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/577,982
				Filing Date	May 2, 2006
				First Named Inventor	Makoto KOIZUMI
				Group Art Unit	
				Examiner Name	
Sheet	2	of	3	Attorney Docket Number	06189/HG

OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS

Examiner Initials ¹	Cite No. ¹	Include name of author (in CAPITAL LETTERS), title of article, title of item, date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		<p>Leonid KRUGLYAK, "Prospects for whole-genome linkage disequilibrium mapping of common disease genes," <u>Nature Genetics</u>, vol. 22, June 1999, pp. 139-144.</p> <p>Henry A. ERLICH et al., "Recent Advances in the Polymerase Chain Reaction," <u>Science</u>, June 21, 1999, Vol. 252, pp. 1643-1651.</p> <p>Koji MORITA et al., "Synthesis and Properties of 2'-O,4'-C-Ethylene-Bridged Nucleic Acids (ENA) as Effective Antisense Oligonucleotides," <u>Bioorganic & Medicinal Chemistry</u>, (2003), Vol. 11, pp. 2211-2226.</p> <p>Koji MORITA et al., "2'-O,4'-C-Ethylene-Bridged Nucleic Acids (ENA): Highly Nuclease-Resistant and thermodynamically Stable Oligonucleotides for Antisense Drug," <u>Bioorganic & Medicinal Chemistry Letters</u>, (2002), Vol. 12, pp. 73-76.</p> <p>Kenneth J. LIVAK, "Allelic discrimination using fluorogenic probes and the 5' nuclease assay," <u>Genetic Analysis: Biomolecular Engineering</u>, (1999), Vol. 14, pp. 143-149.</p> <p>Timothy MORRIS et al., "Rapid Reverse Transcription-PCR Detection of Hepatitis C Virus RNA in Serum by Using the TaqMan Fluorogenic Detection System," <u>Journal of Clinical Microbiology</u>, Dec. 1996, Vol. 34, No. 12, pp. 2933-2936.</p> <p>David LATORRA et al., "Enhanced Allele-specific PCR Discrimination in SNP Genotyping Using 3'Locked Nucleic Acid (LNA) Primers," <u>Human Mutations</u>, (2003), 22:79-85.</p> <p>Peter MOURITZEN et al., "Single nucleotide polymorphism genotyping using locked nucleic acid (LNATM)," <u>Expert Rev. Mole. Diagn.</u>, (2003), 3, PP. 27-38.</p> <p>David LATORRA et al., "Design considerations and effects of LNA in PCR primers," <u>Molecular and Cellular Probes</u>, (2003), 17, pp. 253-259.</p>	
Examiner Signature		Date Considered	

* EXAMINER: Initial if document considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Place a check here if English translation is attached.

DATE MAILED: August 3, 2006

Please type a plus sign (+) inside this box →



PTO/SB/08B (08-00)

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number		10/577,982	
				Filing Date		May 2, 2006	
				First Named Inventor		Makoto KOIZUMI	
				Group Art Unit			
				Examiner Name			
Sheet	3	of	3	Attorney Docket Number		06189/HG	
OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS							
Examiner Initials ¹	Cite No. ¹	Include name of author (in CAPITAL LETTERS), title of article, title of item, date, page(s), volume-issue number(s), publisher, city and/or country where published					T ²
		Björn TEWS et al., "Application of the C4'-Alkylated Deoxyribose Primer System (CAPS) in Allele-Specific Real-Time PCR for Increased Selectivity in Discrimination of Single Nucleotide Sequence Variants," <u>Biol. Chem.</u> , (2003) Vol. 384, pp. 1533-1541. Makoto KOIZUMI et al., "Improvement of single nucleotide polymorphism genotyping by allele-specific PCR using primers modified with an ENA residue," <u>Analytical Biochemistry</u> , (2005), 340, pp. 287-294. Makoto KOIZUMI et al., "SNP genotyping by allele-specific PCR using ENA primers," <u>Nucleic Acid Symposium Ser.</u> , (2005), No. 49, pp. 47-48. Makoto KOIZUMI et al., "Triplex formation with 2'-O,4'-C-ethylene-bridged nucleic acids (ENA) having C3'-endo conformation at physiological pH," <u>Nucleic Acids Research</u> , (2003), Vol. 13, No. 12, pp. 3267-3273. Koji MORITA et al., "2'-O,4'-C-Ethylene-Bridged Nucleic Acids (ENA): Highly Nuclease-Resistant and Thermodynamically Stable Oligonucleotides for Antisense Drug," <u>Bioorganic & Medicinal Chemistry Letters</u> , (2002) 12, pp. 73-76. Masafumi MATSUO et al., "Study of Ability of Antisense ENA to Induce Exon Skipping of Dystrophin Gene," Kosei Rodosho Seishin Shinkei Shikkan Kenkyu Itakuhi ni yoru Kenkyu Hokokushu, Heisei 14 Nendo, July 2003, p. 590.					*
Examiner Signature				Date Considered			

* EXAMINER: Initial if document considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Place a check here if English translation is attached.

DATE MAILED: August 3, 2006

*ENGLISH-LANGUAGE TRANSLATION ENCLOSED